Conference of Radiation Control Program Directors, Inc.

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Dockets Management Branch
HFA-305
Food and Drug Administration
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Rockville, MD 20852

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REF: Docket No. 99N-4578, March 30, 2000 *Federal Register*

The Board of Directors of the Conference of Radiation Control Program Directors, Inc. (CRCPD) wish to submit the following comments on the proposed final rules on State Certification of Mammography Facilities as referenced above. These comments were prepared by the CRCPD's Committee on Mammography and have been endorsed by the CRCPD Board of Directors.

The CRCPD is a nonprofit professional organization made up primarily of the directors and staff of state and local radiation control programs throughout the country. These individuals regulate and control the use of radiation in their jurisdictions and are on the front line in ensuring that the patient, radiation worker, and public are protected from unnecessary exposure from a variety of ionizing radiation sources. Since its inception in 1968, the CRCPD has worked to foster uniformity of radiation control laws and regulations among the states and with the federal agencies.

Subpart C-States as Certifiers

900.21 (a) — Suggest rewording to include that states must have the authority to enter into an agreement with FDA. This implies that the state is more than just capable of entering into such an agreement.

900.21 (b)(iii)(A-0) — Many of these requirements are redundant and should be covered in the applicant agency's draft rules. We recommend shortening the list to the following items:

(A) The rules and regulations to be implemented must be the equivalent of subpart B of FDA's part 900;
(B) Education, experience, and training requirements of the applicant's professional staff;
(C) Statement of policies to avoid conflict of interest;
(D) Description of the applicant's mechanism for handling facility inquires and complaints;
(E) Any other information the FDA identifies as necessary to make a determination on the approval of a state as a certifying agency.

900.22(c) — Suggest rewording this section so as not to imply that the certifying agency is responsible for facility compliance. Remove the word "facility" or add "shall attempt" before "to ensure."

900.22(g) — Patient notification should always occur when an uncertified facility is found to be operating regardless of the clinical image review.

900.22(I) — Suggest rewording "obtain FDA authorization" to "coordinate with FDA to ensure compatibility with MQSA requirements." Although FDA must approve of the regulation changes, we do not feel that FDA can authorize a state to make changes.

99N-4578

C4

General Comments

We recommend changing the term "interim notice" to "interim notice of certification." Since the term refers to a temporary certificate, we felt the second term was clearer.

We felt it could be important to differentiate between new facilities just getting started who are issued an interim notice and those who receive an interim notice due to delays or failures in the reaccreditation process.

There was a concern from some states about the amount of the fee that the FDA would retain being proportionate to the services that FDA will continue to provide to certifying states. Secondly, there is a concern that small states who do not become certifiers will have to carry a disproportionate financial burden as the "pool" of non-certifying states becomes smaller.

The final concern that was raised dealt with the regulations focusing too much on paperwork issues and not enough on the health and safety of the public.

Sincerely,

Charles M. Hardin
Executive Director

CMH/JE/pcg

cc: Board of Directors
Committee on Mammography:
Jennifer Elee, Chairperson (LA)
Aaron Gantt (SC)
Bruce Matkovich (MI)
Don Agnew (IL)
Lin Carigan (OED Staff)
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